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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/067,989	02/08/2002	Randy Dinkins	028750-219	9928

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EXAMINER	
KUBELIK, ANNE R	
ART UNIT	**PAPER NUMBER**
1638	

DATE MAILED: 07/02/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/067,989	DINKINS ET AL.	
	Examiner	Art Unit	
	Anne R. Kubelik	1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-33* is/are pending in the application.

4a) Of the above claim(s) *8,9,15-27,32 and 33* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-7,10-14 and 28-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *24 May 2000* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3 June 2004 has been entered.

2. Claims 1-33 are pending.

3. This application contains claims 8-9, 15-27 and 32-33 drawn to an invention nonelected with traverse in Paper No. 10. A complete reply to the final rejection must include cancellation of nonelected claims and deletion of nonelected subjected matter from the examined claims or other appropriate action (37 CFR 1.144). See MPEP § 821.01.

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

5. The amendment filed 16 September 2003 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material that is not supported by the original disclosure is as follows: The incorporation by reference of 60/267,488.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 USC § 112

6. Claims 1-7, 10-14 and 28-31 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that

was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Neither the instant specification nor the originally filed claims appear to provide support for the phrase "wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell" in claims 1, 10 and 28. Thus, such a phrase constitutes NEW MATTER. In response to this rejection, Applicant is required to point to support for the phrase or to cancel the new matter.

7. Claims 1-7, 10-14 and 28-31 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a vector encoding the *Arabidopsis* MinD protein, plants and cells transformed with it and a method of using it to produce a plant with one or few chloroplasts, does not reasonably provide enablement for vectors comprising a gene encoding a protein with the same functional activity as the *Arabidopsis* MinD protein or having a "significant amount of homology to" the *Arabidopsis* MinD protein, plants and cells transformed with them and a method of using them to produce a plant with one or few chloroplasts. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The rejection is repeated for the reasons of record as set forth in the Office action mailed 3 December 2003. Applicant's arguments filed 3 June 2004 have been fully considered but they are not persuasive.

The claims are broadly drawn to a vector comprising a gene encoding a protein with the same functional activity as the *Arabidopsis* MinD protein or having a "significant amount of

homology to" the *Arabidopsis* MinD protein, plants and cells transformed with it and a method of using it to produce a plant with one or few chloroplasts

The instant specification, however, only provides guidance for isolation of the *Arabidopsis MinD* gene by PCR using primers based on the bacterial gene sequence - the gene was already published in GenBank, (example 1); transformation of the gene into tobacco and analysis of electron transport and chloroplast morphology to show that some plants had very large chloroplasts except in guard cells (examples 1-3); Southern analysis to determine transgene number to show a correlation between abnormal chloroplast morphology and transgene number (examples 4-5); and chloroplast gene expression analysis to show that most genes were expressed normally (example 5).

The instant specification fails to provide guidance for MinD genes having a "significant amount of homology to" the *Arabidopsis MinD* gene. The specification also does not provide guidance for the necessary and sufficient structural features of a MinD protein, and thus of a nucleic acid encoding one

The instant specification also fails to provide guidance for which amino acids of SEQ ID NO:1 can be altered and to which other amino acids, and which amino acids must not be changed, to maintain MinD activity of the encoded protein. The specification also fails to provide guidance for which amino acids can be deleted and which regions of the protein can tolerate insertions and still produce a functional enzyme.

Figure 1 of the instant specification provides an alignment between SEQ ID NO:1 and MinD proteins from *Chlorella*, *Synnechocystis* and *E. coli*. While Applicant may suggest that such an alignment can be used as guidance for making amino acid substitutions, the making of

such substitutions to produce a functional protein is not predictable. Hill et al (1998, Biochem. Biophys. Res. Comm. 244:573-577) teach that three presumably catalytic histidines that are maintained in the same position ADP-glucose pyrophosphorylase across 11 bacterial and plant species (abstract and pg 573, right column, paragraph 3); one would expect that an amino that is so strongly conserved would tolerate either no substitutions or only conservative substations with other basic amino acids. The substitution of one of those histidines with the conservative amino acid arginine drastically reduced enzyme activity; however, substitution with the nonconservative amino acid glutamine, had little effect on enzyme activity (see Table 1). Lazar et al (1988, Mol. Cell. Biol. 8:1247-1252) showed that the "conservative" substitution of glutamic acid for aspartic acid at position 47 reduced biological function of transforming growth factor alpha while "nonconservative" substitutions with alanine or asparagine had no effect (abstract). Thus, amino acid substitution is unpredictable.

Furthermore, it is not clear that the *Chlorella* and *Synnechocystis* proteins are actually MinD proteins. Their identification as such was made purely on homology with the E .coli protein after genomic sequencing (Wakasugi et al, 2001, GenBank Accession No. P56346 and Kaneko et al, 2001, GenBank Accession No. Q55900); there was no establishment of actual protein function.

Given the claim breath, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate nucleic acids encoding derivatives of the *Arabidopsis* MinD protein. Making all possible single amino acid substitutions in an 326 amino acid long protein like that of SEQ ID NO:1 would require making and analyzing 19^{326} nucleic acids. Because nucleic acids encoding derivatives

could encode proteins with many amino acid substitutions, many more than 19^{326} nucleic acids would need to be made and analyzed.

As the specification does not describe the transformation of any plant with a gene encoding a protein with the same functional activity as the *Arabidopsis* MinD protein or encoding a derivative of the *Arabidopsis* MinD protein, undue trial and error experimentation would be required to screen through the myriad of nucleic acids encompassed by the claims and plants transformed therewith, to identify those with a few large chloroplasts, if such plants are even obtainable.

Given the claim breath, unpredictability in the art, undue experimentation, and lack of guidance in the specification as discussed above, the instant invention is not enabled throughout the full scope of the claims.

Applicant urges that genes that encode proteins with the same functional activity as the Arabidopsis MinD gene are taught in the specification on pg 7-9, along with definitions of activity and guidance for determining if the proteins results in the production of fewer and larger chloroplasts (response pg 9).

This is not found persuasive; pages of the specification merely provide ranges of identity or hybridization conditions that a homologous gene might have. Sequences of homologous genes are not taught.

Applicant urges that although the MinD database was created in October 2002, sufficient information was available to one of skill in the art for identification of proteins with the same functional activity as the Arabidopsis MinD gene, and Fig. 1 shows an alignment of several

MinD homologs, showing which amino acids are conserved between species and which are not (response pg 10).

This is not found persuasive because the specification does not teach the sequences of homologous genes within the full scope of the claims; for example, no other plant MinD gene is taught. See *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ 2d 1016 at page 1016:

> Conception of chemical compound requires that inventor be able to define compound so as to distinguish it from other materials, and to describe how to obtain it, rather than simply defining it solely by its principal biological property; thus, when inventor of gene, which is chemical compound albeit complex one, is unable to envision detailed constitution of gene so as to distinguish it from other materials, as well method for obtaining it, conception is not achieved until reduction to practice has occurred, and until after gene has been isolated ... Conception of generalized approach for screening DNA library that might be used to identify and clone erythropoietin gene of then-unknown constitution is not conception of 'purified and isolated DNA sequence' encoding human EPA, since it is not 'definite and permanent idea of the complete and operative invention'." and at pg 1027 "... despite extensive statements in the specification concerning all the analogs of the EPO gene that can be made, there is little enabling disclosure of particular analogs and how to make them. Details for preparing only a few EPO analog genes are disclosed. Amgen argues that this is sufficient to support its claims; we disagree. This "disclosure" might well justify a generic claim encompassing these and similar analogs, but it represents inadequate support for Amgen's desire to claim all EPO gene analogs.
> There may be many other genetic sequences that code for EPO-Type products. Amgen has told how to make and use only a few of them and is therefore not entitled to claim all of them.

8. Claims 1-7, 10-14 and 28-31 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The rejection is repeated for the reasons of record as set forth in the Office action mailed 3 December 2003. Applicant's response filed 3 June 2004 does not address this rejection.

The claims are broadly drawn to a multitude of a vector encoding a derivative of the *Arabidopsis* MinD protein, methods of its use, and cells and plants comprising it.

In contrast, the specification only describes a coding sequence from *Arabidopsis* that encodes SEQ ID NO:1. Applicant does not describe other DNA molecules encompassed by the

claims, and the structural features that distinguish all such nucleic acids from other nucleic acids are not provided.

Hence, Applicant has not, in fact, described DNA molecules that encode a derivative of the *Arabidopsis* MinD protein within the full scope of the claims, and the specification fails to provide an adequate written description of the claimed invention.

Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, it is not clear that Applicant was in possession of the genus claimed at the time this application was filed.

9. Claims 1-7, 10-14 and 28-31 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Dependent claims are included in all rejections. The rejection is repeated for the reasons of record as set forth in the Office action mailed 3 December 2003. Applicant's arguments filed 3 June 2004 have been fully considered but they are not persuasive.

Claims 1, 5-7, 10-13 and 28-31 are indefinite in their recitation of "exogenous". It is not clear to what the gene is exogenous - the vector? *Arabidopsis*? a randomly chosen plant?

Applicant urges that the claims have been amended to obviate this rejection (response pg 11).

This is not found persuasive because whether a particular vector is encompassed by the claims would depend upon the intended use of the vector - a vector comprising the Arabidopsis MinD gene would be encompassed if one intended to use it to transform tobacco, but not if one

intended to use it to transform Arabidopsis, even though the vector itself has not changed. The phrase is indefinite because a product must be encompassed by or excluded from the claim under all circumstances.

Claims 1, 10 and 28 are indefinite in their recitation of "a protein with the same functional activity as a protein encoded by the *Arabidopsis thaliana* ... *MinD* gene". It is unclear which protein encoded by the *MinD* gene is being referred to. Additionally, it is not clear what the exact function of the *Arabidopsis* MinD protein - what proteins does it interact with, what is its exact enzymatic activity?

Applicant urges that the function of the MinD protein is clearly defined on pg 13 of the specification as "resulting in the production of fewer and larger chloroplasts", and that any protein encoded by the MinD gene that resulted in the production of fewer and larger chloroplasts would be encompassed by the claims (response pg 11-12).

This is not found persuasive because several different proteins, when over or under expressed in a plant have this activity, yet they would not be called MinD proteins by other measures of function, for example GTPase activity. How is "MinD gene" defined?

Claims 1, 10 and 28 are indefinite in their recitation of "wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell". It is unclear what level of hybridization this is, as all nucleic acids will "cross-hybridize" with all other nucleic acids under at least some conditions.

Applicant urges that cross-hybridization details are described in the specification at pg 8-9, and thus a skilled artisan, using that and what is known in the art would appreciate the meaning of the phrase (response pg 12).

This is not found persuasive. The hybridization conditions listed are only non-limiting examples and the specification specifically indicates that.

Claims 5, 7, 11, 13, 29 and 31 are indefinite in their recitation of "significant amount of homology to a gene from of Arabidopsis thaliana". It is unclear what gene the exogenous gene has homology to and it is unclear what level of homology is "significant".

Applicant urges that one of skill in the art would appreciate the meaning as homology is defined in the specification and known in the art (response pg 12).

This is not found persuasive. Where does the specification define what level of homology is "significant"?

Claims 29-30 lack antecedent basis for the limitation "The vector of Claim 28" as claim 28 is drawn to a method. Amendment to address this rejection will affect dependent claims.

Claim Rejections - 35 USC § 102

10. Claims 1-7, 10-13 and 28-31 remain rejected under 35 U.S.C. 102(a) as being anticipated by Colletti et al (2000, Curr. Biol. 10:507-516). The rejection is repeated for the reasons of record as set forth in the Office action mailed 3 December 2003. Applicant's arguments filed 3 June 2004 have been fully considered but they are not persuasive.

Colletti et al teach vectors comprising the *Arabidopsis MinD* coding sequence in the sense or antisense orientation under control of the 35S promoter and *Arabidopsis* plants whose nuclear genome is transformed with the gene (pg 508, right column, paragraph 3; pg 511, left column, paragraph 2); these plants had large chloroplasts that were reduced in number (pg 509, right column, paragraph 3; pg 511, left column, paragraph 2). Seeds of transformed plants were

generated in the production of T1-T3 progeny (pg 508, right column, paragraph 3; pg 511, left column, paragraph 2). The *Arabidopsis MinD* coding sequence would not "cross-hybridize" with the MinD gene of non-Arabidopsis thaliana plant MinD genes, at least under some hybridization conditions.

Applicant urges that although Colletti describes vectors comprising an Arabidopsis MinD gene, these vectors are expressed in an Arabidopsis plant cell and would cross-hybridize with the homologous gene in the plant cell; Colletti does not describe the limitation that the gene is an exogenous gene that does not cross-hybridize with a homologous gene of the plant cell (response pg 13).

This is not found persuasive because the recitation "wherein the exogenous gene does not cross-hybridize with an homologous gene of the plant cell" for the vector is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

The method of claim 28 does not require that the exogenous gene not cross-hybridize with a plant cell in the plant into which the vector is transformed; it only requires that the gene not "cross-hybridize with "a" plant cell.

It is noted that the vector of Colletti et al and the vector taught on pg 20, lines 7-26 of the instant specification both comprise the Arabidopsis MinD coding sequence operably linked to the 35S promoter.

Applicant urges that the vectors, plants and methods of Colletti do not inherently disclose a system of increased efficiency; just because a certain result may be present is not sufficient to establish inherency (response pg 13).

This is not found persuasive because the method steps taught by Coletti are identical to the instantly claimed method steps.

Applicant urges that as described in Example 12 in the specification, the claim limitations related to exogenous genes are necessary to prevent gene silencing (response pg 14).

This is not found persuasive because Example 12 is drawn to use of AtMinE1, not MinD. Furthermore, in that example "cross-hybridization" was required to get antisense suppression.

11. Claims 1-7, 10-13 and 28-31 remain rejected under 35 U.S.C. 102(a) as being anticipated by Kanamaru et al (2000, Plant Cell Physiol. 41:1119-1128 and GenBank Accession No. AB030278, December 2000). The rejection is repeated for the reasons of record as set forth in the Office action mailed 3 December 2003. Applicant's arguments filed 3 June 2004 have been fully considered but they are not persuasive.

Kanamaru et al teach a vector comprising the *Arabidopsis MinD* gene (GenBank Accession No. AB030278) under control of the 35S promoter and *Arabidopsis* plants whose nuclear genome is transformed with the gene; these plants had large chloroplasts that were reduced in number (Figure 6). Seeds of transformed plants were generated in the production of T2 and T3 progeny (pg 1121, left column, paragraph 2). The *Arabidopsis MinD* coding

sequence would not "cross-hybridize" with the MinD gene of non-Arabidopsis thaliana plant MinD genes, at least under some hybridization conditions.

Applicant urges that although Kanamaru describes vectors comprising an Arabidopsis MinD gene, these vectors are expressed in an Arabidopsis plant cell and would cross-hybridize with the homologous gene in the plant cell and Kanamaru does not describe the limitation that the gene is an exogenous gene that does not cross-hybridize with a homologous gene of the plant cell (response pg 14).

This is not found persuasive because the recitation "wherein the exogenous gene does not cross-hybridize with an homolous gene of the plant cell" for the vector is a recitation of intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

The method of claim 28 does not require that the exogenous gene not cross-hybridize with a plant cell in the plant into which the vector is transformed; it only requires that the gene not "cross-hybridize with "a" plant cell.

Applicant urges that the vectors, plants and methods of Colletti do not inherently disclose a system of increased efficiency; just because a certain result may be present is not sufficient to establish inherency (response pg 13-14).

This is not found persuasive because the method steps taught by Kanamaru are identical to the instantly claimed method steps.

Applicant urges that as described in Example 12 in the specification, the claim limitations related to exogenous genes are necessary to prevent gene silencing (response pg 15).

This is not found persuasive because Example 12 is drawn to use of AtMinE1, not MinD. Furthermore, in that example "cross-hybridization" was required to get antisense suppression.

12. Claims 1-2 and 5-7 remain rejected under 35 U.S.C. 102(b) as being anticipated by Huang et al (1996, J. Bacteriol. 178:5080-5085). The rejection is repeated for the reasons of record as set forth in the Office action mailed 3 December 2003. Applicant's arguments filed 3 June 2004 have been fully considered but they are not persuasive.

Huang et al teach expression vectors encoding a bacterial MinD protein and yeast cells comprising the vector; the bacterial protein would have the same function as the *Arabidopsis* MinD protein (pg 5083, left column, paragraph . Furthermore, the bacterial gene would not cross-hybridize to the endogenous MinD gene of a plant cell.

Applicant urges that Huang does not describe the claim limitation that the gene is an exogenous gene that does not cross-hybridize with a homologous gene of the plant cell (response pg 16).

This is not found persuasive because the yeast gene would be exogenous to all plants and would not be identical to any plant gene and thus would not "cross-hybridize" to one.

Applicant urges that the methods disclosed by Huang do not inherently disclose a system of increased efficiency (response pg 16).

This is not found persuasive because the rejection is not applied to any method steps.

Conclusion

13. No claim is allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne R. Kubelik, whose telephone number is (703) 308-5059. The examiner can normally be reached Monday through Friday, 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

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Anne R. Kubelik, Ph.D.
June 29, 2004

ANNE KUBELIK
PATENT EXAMINER